

510(k) SUMMARY**A. Submitter information**

- Applicant's Name: Company name: ATYS Sarl
Managing Director: Denis PARZY
- Applicant's Address: 17 Parc d'activités d'Arbora
69510 SOUCIEU EN JARREST
FRANCE
- Telephone Number: 33 (0)4 78 05 69 69
- Contact Person: Christine TURLAT, Ph.D.

B. Device identification

- Proprietary Name:
BASIC, including three models: BASIC 1, BASIC 2 and BASIC 3.
- Common Name: Vascular test system: peripheral Doppler with photo & pneumo plethysmography.
- Class: Regulatory Class II

C. Identification of predicate device

Predicate Devices:
HOKANSON, TL 400 TOTALAB (K872517).
BIOMEDIX, FLOSTAT VASCULAR LAB (K973644)
IMEX MEDICAL SYSTEMS, IMEXLAB 9100 (K973562)

D. Performance standards

Conforms to the following voluntary standards: IEC 601-1, EN 60601-1-2, IEC 801-2,3,4,5
EN55011 (CISPR11).
The quality system is ISO 9001 and EN 46001 approved and certified.

E. Special Controls

510(k) Special Report

F. Indications for Use

The BASIC is a non-invasive diagnostic system to assist in the detection of peripheral vascular disease (arterial or venous).

The BASIC is not intended to be used for fetal monitoring nor for fetal applications. The BASIC is not intended for ophthalmic applications.

The BASIC is not intended for home use.

The BASIC is not intended for use on non-intact skin or eyes.

G. device description

The diagnosis with the BASIC is performed via four separate modalities, each of which can be used to test either the arterial or venous system.

These four modalities are:

- 4 and 8 MHz continuous wave Doppler.
- Photoplethysmography,
- Air plethysmography,
- Systolic pressure examination.

The **BASIC's** principle of operation is based on:

- Doppler mode: the real time ultrasound measurement of blood velocity in the examined vessel. The time evolution of the blood velocity in the examined vessel is displayed as a waveform. The measurement of the velocity is made with a 4 or 8 MHz probe.
- Photoplethysmography: The photo plethysmography probe is placed on a digit or taped to the skin surface. The photo plethysmography probe contains an infrared light source and a sensitive photocell. The light source directs infrared light into the skin. The receiving photocell measures the amount of light reflected off the blood cells. So, the photoplethysmography measures in real time the change of the amount of blood in the skin tissue with each contraction of the heart. It depicts it in a waveform.
- Air plethysmography: the real time measure of the change of blood volume in a limb. An Air-filled pressure cuff is used to measure these changes. By wrapping a pressure cuff around different locations on a patient's leg, arm or digit, the blood flow at these locations can be quickly assessed. Relative limb volume increases with each heart beat. Air plethysmography measures this increase and depict it in a waveform.
- Systolic pressure examination requires a Doppler probe or an arterial photoplethysmography sensor and a pressure cuff to measure the patient's systolic pressure at different locations (legs, arms, digits).

The important data are not the absolute value of the pressures but the pressure differences or ratio.

The **BASIC** consists of the following components:

- The main console,
- The 4 and 8 MHz probes,
- The photo-plethysmography sensors,
- The cuffs (the cuffs are accessories not manufactured by Atys).

The main consoles provides various indicators and controls designed to lead the operator through the sequential procedures needed for the operation of the BASIC. It contains a LCD screen and a thermal printer to display the parameters and charts associated with the tests. The console also houses the electrical and electronical components, the cuff inflate pump,

the pressure sensor (that measures the pressure in the cuff). The device operates from a 110-220 V supply.

The 4 and 8 MHz probes are comprised of a sensor tip, a mechanical head, a cable and a connector. The sensor tip comprises either two piezo electric transducers.

The transducer transforms the electrical energy into acoustical energy and vice versa.

The photo sensors are non focused sensors with two (arterial sensors) or four (vein sensors) emitters and a center receiver.

H. Acoustic Output

Maximum acoustic output levels are below pre-amendment levels (track 1) for acoustic intensity for the investigation of peripheral vessels.

I. Substantial Equivalence

The technical characteristics are almost identical to those of the

- HOKANSON TL, 400 TOTALAB (K872517)
- BIOMEDIX, FLOSTAT VASCULAR LAB (K973644)
- IMEX MEDICAL SYSTEMS, IMEXLAB 9100 (K973562)

previously cleared predicate devices.

Differences that exist between these devices in terms of technical specifications, ultrasonic technology, functions, performances, and methods of applications do not affect the relative safety or effectiveness of the **BASIC**.

Accordingly, the BASIC is believed to be substantially equivalent to devices of the same type that are currently lawfully distributed in interstate commerce in United State.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 1 0 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ATYS Medical
% Mr. Mark Job
510(k) Program Manager
TUV Product Service, Inc.
1775 Old Highway 8 NW
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K012369
BASIC 1, 2, and 3 (Peripheral Vascular Diagnostic Test System)
Dated: July 23, 2001
Received: July 26, 2001
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 870.2780/Procode: 74 JOM

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: ATYS

510(k) Number (if known):

K012369

Device Name: BASIC

Indications For Use:

- Photo-plethysmography module.
- Pneumo-plethysmography module.

The pneumo-plethysmography module measures volume changes in limbs or digits. Relative limb volume increases with each heartbeat. The pneumo-plethysmography module measures this increase and depicts it as a waveform.

The pneumo-plethysmography is also used in conjunction with the Doppler module or the photo-plethysmography module to measure the systolic blood pressure in limbs or digits. In this case, the pneumo-plethysmography module is used to inflate a cuff to perform the occlusion.

The photo-plethysmography module; the amount of blood in the skin changes with each contraction of the heart. The Photo-plethysmography module measures this change and depicts it in a waveform.

The photo-plethysmography module is also used in conjunction with the pneumo-plethysmography module (blood pressure cuffs) to measure the systolic blood pressure. The photo-plethysmography module detects the return of the blood after the occlusion.

The pneumo-plethysmography module is not intended for neonatal applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use



(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

Nancy C. Brogan

K012369

RA
II

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|---|-----|-----|---------------|-------------------|------------------------|--------------------|-----------------|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | N | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: BASIC - Peripheral Doppler
8MHz Transducer

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K012369

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|---|-----|-----|---------------|-------------------|------------------------|--------------------|-----------------|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | N | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: BASIC - Peripheral Doppler
4 MHz Transducer

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 Concurrence of CDH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K012369

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|---|-----|-----|---------------|-------------------|------------------------|--------------------|-----------------|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | N | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: BASIC - Peripheral Doppler
4 and 8 MHz transducers

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 510(k) Number K012369

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